

CP



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/392,842 | 09/09/1999 | SAMUEL P. SAWAN | SUR-008 | 1863 |

7278 7590 08/10/2004

DARBY & DARBY P.C.
 P. O. BOX 5257
 NEW YORK, NY 10150-5257

EXAMINER

SHARAREH, SHAHNAM J

ART UNIT PAPER NUMBER

1617

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/392,842

Applicant(s)

SAWAN ET AL.

Examiner

Shahnam Sharareh

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 58,60,62-71 and 89-101 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 58,60,62-71 and 89-101 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on April 19, 2004 has been entered.

Claims 58, 60, 62-71, 89-101 are pending.

Prosecution on the elected bigunide polymer specie of poly(hexamethylenebiguanide) ("PHMB"), and water-insoluble organic compound specie of methylene-bis-N,N-diglycidylaniline, ("MBDGA") as set forth in Paper No. 8, is hereby continued.

Any rejection that is not addressed in this Office Action is considered obviated in view of the amendments and the arguments.

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory

Art Unit: 1617

double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 58, 60, 62-71, 89-101 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-38 of U.S. Patent No. US 6,180,584, claims 1-6 US Patent 6,030,632, claims 1-9, US Patent 5,869,072, claims 1-9, US Patent 5,817,325. Although the conflicting claims are not identical, they are not patentably distinct from each other because each of the cited patents are directed to compositions comprising a biguanide material, a metal material such as silver compounds and a cross linker, and/or methods of using such compositions to improve the antimicrobial activity of an article or a secondary formulation.

For example, claims of the patent 6,018,584 are directed to methods of providing antimicrobial activity on skin by applying the claimed invented disinfectant composition on a substrate (claims 1, 27-33). The instant claims differ from the patented claims only by the nature of the substrate. However, it would have been obvious to one of ordinary skill in the art at the time of invention to employ the compositions of the patented claims on suitable substrates including scrubs, skin preparations directly or through suitable carrier systems. Accordingly, the instant claims are obvious modification of the already patented claims.

Examiner noted Applicant statement indicating that an appropriate terminal disclaimer will be filed once allowable subject matter is determined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 58-60, 68-71, 89-101 are rejected under 35 U.S.C. 102(e) as being anticipated by Fujiwara et al US Patent 6,071,866.

Instant claims are directed to methods of (a) providing antimicrobial activity on skin comprising administering a biguanide polymer, a metallic material and a skin compatible component and (b) forming a moisture-resistant film on the skin to provide antimicrobial activity.

Fujiwara discloses liquid skin cleanser compositions in the form of lotion or cream comprising a PHMB which is a biguanide polymer, a metallic material such as sodium laureth sulfate or sodium olefin sulfonate which falls within the scope

Art Unit: 1617

of the instant metallic materials as described in page 7 of the specification. (see col 6, lines 20-24; col 8, lines 5-7; col 12, lines 34-55). Fujiwara also teaches other skin compatible components such as lactic acid and surfactants, to formulate a topical cleansing formulation. Fujiwara performs tests to assess the antimicrobial activity of the composition (col 9-12). Since the compositions of Fujiwara meets all elements of the compositions employed in the step (a) of the instant claims, formation of a moisture-resistant film and the properties of the film (i.e. sweat resistant) would be an inherent function of such skin compositions of Fujiwara when it is applied to skin, because such function are inseparable from the composition upon its application to skin.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 58, 60, 62-71, 89-101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujiwara in view of Sawan et al WO 95/17152 ('152) and Smith US Patent 5,576,006.

The teachings of Fujiwara are described above. Fujiwara fails to employ a silver salt in his composition as an adjunct antimicrobial agent. Fujiwara also fails to use a water-insoluble organic to cause cross-linking of PHMB.

Sawan '152 teaches that the cross-linking of PHMB with a water-insoluble organic compound such as MBDGA enhances the final activity. Swan also teaches the use of silver salts as a bactericidal metallic material (see pages 25-29, page 65, lines 3-20). It is well established in the art that silver salts of Swan are bactericidal material and that they are readily used for topical applications.

Smith is complementary to Fujiwara and Sawan as it provides the state of art for preparing topical PHMB containing lotions (see col 3, line 39-col 4, line 50).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to cross link PHMB of Fujiwara with MBDGA of Sawan and further as described in Smith prepare a topical formulation of choice such as a lotion or solution. The ordinary skill in the art would have made such modification to Fujiwara's composition, because he would have had a reasonable expectation of success to enhance therapeutic effects of Sawan's antibacterial activity when administered topically.

Further, since both PHMB and Silver salts provide antibacterial properties, one of ordinary skill in the art at the time of invention would have been motivated

Art Unit: 1617

to add a silver salt to compositions of Fujiwara to enhance antimicrobial activity of such compositions, because it is *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art. *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).


Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnaz Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200